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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,010	10/12/2000	YOSHIAKI HATA	15162/02600	6171

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EXAMINER

BARTON, JEFFREY THOMAS

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No. 09/689,010	Applicant(s) HATA, YOSHIAKI	
	Examiner Jeffrey T. Barton	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 9-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20001212</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 2 is objected to because of the following informalities: in line 4 of the claim, the word "oppose" is used, although "opposed" appears to have been intended. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Kennedy.

Regarding claim 1, Kennedy discloses a chip comprising a channel with analytes passing therethrough. (Figure 1) and an optical element (Window) facing the channel to receive light from the analytes (fluorescence), said optical element forming a part of the internal surface of the channel. (Column 7, lines 30-65)

Art Unit: 1753

Regarding claim 2, Kennedy discloses the channel being formed by a groove on a first surface of a substrate (Column 4, lines 27-36), wherein the substrate has a second surface opposed to the first surface and has a through hole connecting the bottom of the groove to the second surface, and the optical element is provided in said hole. (The hole in Kennedy's device passes through both substrates, providing the window in the case of opaque substrate materials. Nevertheless, it does connect the bottom of the groove to the second surface, and therefore reads on the claimed device.)

Regarding claim 4, Kennedy discloses a cover plate covering a portion of the groove. (Column 4, lines 27-36)

4. Claims 1, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Pace.

Regarding claim 1, Pace discloses a chip comprising a channel with analytes passing therethrough. (Figure 3; Column 3, line 52 - Column 4, line 11) and an optical element (Plate 38 functions as a window) facing the channel to receive light from the analytes (Fluorescence; Column 8, lines 11-21), said optical element forming a part of the internal surface of the channel. (Figure 3)

Regarding claim 6, Pace discloses numerous electrodes disposed on internal surfaces of the channel, partially disposed on the optical element. (Plate 38) (Figures 2 and 3; electrodes 12)

Regarding claim 7, Pace discloses the objects (analytes) traveling through the channel in a traveling direction (Figure 1, left to right; Column 6, lines 11-23), wherein

Art Unit: 1753

the second electrode is provided at an upstream side of the optical element. Pace shows several electrodes disposed at the upstream end of the channel 10 in Figure 1, which would also correspond to the upstream side of the optical element, Plate 38, with an arrangement such as that shown in Figure 7. Furthermore, in Figure 1, the majority of electrodes are upstream of the detector 22, which is the only point at which plate 38 functions as the optical element as claimed.

5. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Manz et al.

Regarding claim 1, Kaltenbach discloses a chip comprising a channel with analytes passing therethrough. (Figures 3 and 4, channel 21) and an optical element (Fiber 13) facing the channel to receive light from the analytes, said optical element forming a part of the internal surface of the channel.

Regarding claim 8, Kaltenbach discloses a light guide (Figure 4, Fiber 12) for guiding a light from an external source to an area of the channel (the portion between Fibers 13 and 13), wherein the element (13) is provided at the prescribed area.

6. Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaltenbach.

Regarding claim 1, Kaltenbach discloses a chip comprising a channel with analytes passing therethrough. (Figure 5, channel 108) and an optical element (Fiber

Art Unit: 1753

512) facing the channel to receive light from the analytes, said optical element forming a part of the internal surface of the channel.

Regarding claim 8, Kaltenbach discloses a light guide (Figure 5, Fiber 510) for guiding a light from an external source to an area of the channel (the portion between Fibers 510 and 512), wherein the element (512) is provided at the prescribed area.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 1753

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manz et al in view of Kricka et al.

Manz et al disclose a device as described above in addressing claim 1.

Relevant to claim 2, Manz et al also disclose a chip wherein a substrate (Figure 4, plate 5) has a second surface (top, as shown in Figure 4) opposed to a first surface and has a through hole (11) with the optical element (13) disposed therein.

Relevant to claim 3, Manz et al disclose the through hole (11) having a tapered shape. (Figure 4)

Relevant to claim 4, Manz et al disclose a plate (6) provided on the first surface of the substrate (5). (Figure 4)

Manz et al do not explicitly disclose the channel being defined in part by a groove on the first surface (interior) of substrate (5).

Kricka et al disclose formation of channel grooves in a microfluidic device on the same substrate as through-holes that provide access to the channels. (i.e. the channel is defined by a groove on one surface and holes connect the bottom of the groove to the

opposing surface - see Figures 2 and 4) The device of Kricka et al is made of the same material (crystalline silicon) as is preferred by Manz et al.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Manz et al by fabricating the channel on the inward-facing surface of substrate 5, instead of plate 6, as taught by Kricka et al, because it would simplify device construction by allowing channel paths to be directly defined by through hole locations (i.e. channel etching could be guided by hole locations after through-hole etching), and eliminating concerns over the alignment of plates relative to each other.

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy.

Kennedy discloses a chip as described above in addressing claim 2.

Kennedy does not explicitly disclose the through hole having a tapered shape.

However, it is well within the abilities of one having ordinary skill in the art to select a shape suitable for the hole that accommodates the detection window. For instance, in *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966), the court held that the configuration (i.e. shape) of the claimed object was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.

Furthermore, Kennedy discloses forming the chip from silicon (Column 3, line 65 - Column 4, line 4), and conventional etching techniques (KOH) typically attack silicon anisotropically, resulting in tapering pits, trenches, or holes.

Art Unit: 1753

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy in view of Weigl et al.

Kennedy discloses a device as described above in addressing claim 1. Kennedy further describes a broad range of detectors suitable for use with his chip. (Column 7, lines 46-65)

Kennedy does not explicitly disclose a device comprising an optical element comprising a condenser lens.

Weigl et al disclose a detector comprising a condenser lens useful in combination with microfluidic devices. (Figure 1, lens 50, cartridge 34 corresponds to the microfluidic device - see background section; also Column 4, lines 16-40)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Kennedy to include the detector taught by Weigl et al, because they teach its usefulness in detecting multiple analytes at multiple wavelengths (Column 3, lines 7-15), and electrophoresis devices, such as that of Kennedy, are often used for analysis of multicomponent samples.

In this rejection, given the open language of the claims (i.e. "comprising") the limitation "optical element having a surface forming part of the internal surface of the channel" is read broadly such that a detection system comprising both a window that forms part of the channel's internal surface and a condenser lens is held to read on the claim limitations.

Art Unit: 1753

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy in view of Swerdlow et al.

Kennedy discloses a device as described above in addressing claim 1. Kennedy further describes a broad range of detectors suitable for use with his chip. (Column 7, lines 46-65)

Kennedy does not explicitly disclose a device comprising an optical element comprising a condenser lens.

Swerdlow et al describe a detector comprising a lens that "condenses" light emitted over a range of angles into a converging beam, wherein the detector is used in combination with a capillary flow cell. (Figure 3, objective lens)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Kennedy to include the detector described by Swerdlow et al, because they teach its extremely high sensitivity. (Abstract)

14. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pace in view of either Weigl et al or Swerdlow et al.

The reasoning for this rejection parallels that given above in paragraphs 12 and 13.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571)


Art Unit: 1753

272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
December 23, 2004


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